



U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

FIFTH SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT  
(Use several sheets if necessary)

ATTY. DOCKET NO. 110129.430	APPLICATION NO. 10/673,046
APPLICANTS	
David M. Gravett et al.	
FILING DATE September 26, 2003	GROUP ART UNIT 1614

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA						
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
BF	AK	WO 99/33455 A1	07/08/99	WIPO	—	—
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## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER	/Blessing Fubara/	DATE CONSIDERED	09/18/2006
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 110129.430	APPLICATION NO. 10/673,046
SIXTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS David M. Gravett et al.	
		FILING DATE September 26, 2003	GROUP ART UNIT 1614

*FEB 09 2006*

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	AA	2004/0167572 A1	08/26/04	Roth et al.	606	219	/
BF	AB	2004/0193177 A1	09/30/04	Houghton et al.	606	108	
BF	AC	2004/0236416 A1	11/25/04	Falotico	623	1.42	
BF	AD	2005/0004663 A1	01/06/05	Llanos et al.	623	1.46	
BF	AE	2005/0033417 A1	02/10/05	Borges et al.	623	1.46	
BF	AF	2005/0136090 A1	06/23/05	Falotico et al.	424	423	
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## FOREIGN PATENT DOCUMENTS

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Sheet 1 of 1

FORM;PTO-1449 (REV.7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 110129.430	APPLICATION NO. 10/673,046
2ND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS David M. Gravett et al.		
		FILING DATE September 26, 2003	GROUP ART UNIT 1614	

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	AA	2003/0225355 A1	12/04/03	Butler	602	48	—
BF	AB	6,726,923 B2	04/27/04	Iyer et al.	424	433	—
	AC						
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### FOREIGN PATENT DOCUMENTS

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		3RD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS <b>David M. Gravett et al.</b>	
		FILING DATE <b>September 26, 2003</b>		GROUP ART UNIT <b>1614</b>	

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	AA	2003/0083733 A1	05/01/03	Kunz	623	1.15	
	AB	2003/0100600 A1	05/29/03	Kinsella et al.	514	449	
	AC	5,455,039	10/03/95	Edelman et al.	424	422	
	AD	5,527,532	06/18/96	Edelman et al.	424	422	
	AE	5,540,928	07/30/96	Edelman et al.	424	422	
	AF	5,616,608	04/01/97	Kinsella et al.	514	449	
	AG	5,733,925	03/31/98	Kunz et al.	514	449	
	AH	5,981,568	11/09/99	Kunz et al.	514	411	
	AI	6,074,659	06/13/00	Kunz et al.	424	423	
	AJ	6,268,390 B1	07/31/01	Kunz	514	411	
	AK	6,306,421 B1	10/23/01	Kunz et al.	424	423	
	AL	6,326,017 B1	12/04/01	Mayberg	424	422	
	AM	6,358,989 B1	03/19/02	Kunz et al.	514	411	
	AN	6,515,009 B1	02/04/03	Kunz et al.	514	411	
	AO	6,534,693 B2	03/18/03	Fischell et al.	602	43	
	AP	6,569,441 B2	05/27/03	Kunz et al.	424	423	
	AQ	6,663,881 B2	12/16/03	Kunz et al.	424	423	
▼	AR	6,720,350 B2	04/13/04	Kunz et al.	514	411	
BF	AS	6,759,431 B2	07/06/04	Hunter et al.	514	449	

## FOREIGN PATENT DOCUMENTS

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FORM PTO-1449  
(REV.7-80)

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**SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**  
(Use several sheets if necessary)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
110129.430APPLICATION NO.  
10/673,046

## APPLICANTS

David M. Gravett et al.

FILING DATE

September 26, 2003

GROUP ART UNIT

1640

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	AA	2003/0003094	01/02/03	Hunter et al.	424	94.63	—
BF	AB	2004/0013703	01/22/04	Ralph et al.	424	426	—
	AC						
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
BF	AK	EP 689807 A2	01/03/96	EPO		
BF	AL	EP 1155689 A2	11/21/01	EPO		
BF	AM	WO 00/40278	07/13/00	WIPO		
BF	AN	WO 02/056790	07/25/02	WIPO		
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## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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## DATE CONSIDERED

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FORM PTO-144 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 110129.430	APPLICATION NO. 10/673,046
MAY 19 2004 U.S. PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS David M. Gravett et al.			
		FILING DATE September 26, 2003		GROUP ART UNIT 1614	

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	AA	5,612,052	03/18/97	Shalaby	424	426	
	AB	5,702,826	12/30/97	Ehret et al.	428	515	
	AC	5,714,159	02/03/98	Shalaby	424	426	
	AD	6,258,823	07/10/01	Holt et al.	514	291	
	AE	6,413,539	07/02/02	Shalaby	424	426	
▼	AF	2002/0123505	09/05/02	Mollison et al.	514	291	
BF	AG	2003/0152609	08/14/03	Fischell et al.	424	445	
	AH						
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
BF	AK	EP 184162 B1	04/27/94	EPO		
	AL					
	AM					
	AN					
	AO					

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BF	AP		Arshady, R., "Preparation of biodegradable microspheres and microcapsules: 2. Polyactides and related polyesters," <i>Journal of Controlled Release</i> 17: 1-22, 1991.
BF	AQ		Bae, Y.H. et al., " 'On-Off' Thermocontrol of Solute Transport. I. Temperature Dependence of Swelling of <i>N</i> -Isopropylacrylamide Networks Modified with Hydrophobic Components in Water," <i>Pharmaceutical Research</i> 8(4): 531-537, 1991.
BF	AR		Bae, Y.H. et al., " 'On-Off' Thermocontrol of Solute Transport. II. Solute Release from Thermosensitive Hydrogels," <i>Pharmaceutical Research</i> 8(5): 624-628, 1991.

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	BA						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO
	BB				

**OTHER ART** (Including Author, Title, Date, Pertinent Pages, Etc.)

BF	BC		Bawa, R. et al., "An Explanation for the Controlled Release of Macromolecules from Polymers," <i>Journal of Controlled Release</i> 1: 259-267, 1985.
	BD		Brown, L.R. et al., "In Vivo and In Vitro Release of Macromolecules from Polymeric Drug Delivery Systems," <i>Journal of Pharmaceutical Sciences</i> 72(10): 1181-1185, October 1983.
	BE		Cascone, M.G. et al., "Collagen and hyaluronic acid based polymeric blends as drug delivery systems for the release of physiological concentrations of growth hormone," <i>Journal of Materials Science: Materials in Medicine</i> 5: 770-774, 1994
	BF		Chen, G. et al., "Novel Hydrogels of a Temperature-Sensitive Pluronic® Grafted to a Bioadhesive Polyacrylic Acid Backbone for Vaginal Drug Delivery," in <i>1995 Proceedings of the 22nd International Symposium on Controlled Release of Bioactive Materials</i> , Controlled Release Society, Deerfield, IL, 1995, pgs. 167-168.
	BG		Chun and Kim, "A novel hydrogel-dispersed composite membrane of poly( <i>N</i> -isopropylacrylamide) in a gelatin matrix and its thermally actuated permeation of 4-acetaminophen," <i>Journal of Controlled Release</i> 38: 39-47, 1996.
	BH		Cornejo-Bravo, J.M. et al., "Kinetics of drug release from hydrophobic polybasic gels: effect of buffer acidity," <i>Journal of Controlled Release</i> 33: 223-229, 1995.
	BI		Dinarvand and D'Emanuele, "The use of thermoresponsive hydrogels for on-off release of molecules," <i>Journal of Controlled Release</i> 36: 221-227, 1995.
	BJ		Doelker, E., "Cellulose Derivatives," in <i>Advances in Polymer Science 107: Biopolymers I</i> , Peppas and Langer (eds.), Springer-Verlag, Berlin, 1993, pgs. 200-265.
↓	BK		Dong and Hoffman, "A novel approach for preparation of pH-sensitive hydrogels for enteric drug delivery," <i>Journal of Controlled Release</i> 15: 141-152, 1991.
BF	BL		Dong, L-C et al., "Controlled release of amylase from a thermal and pH-sensitive macroporous hydrogel," <i>Journal of Controlled Release</i> 19: 171-178, 1992.

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	CA						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
	CB				YES NO

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BF	CC	Dunn, E.J. et al., "Synthesis of N-(aminoalkyl) chitosan for Microcapsules," <i>Journal of Applied Polymer Science</i> 50(2): 353-365, October 10, 1993.
	CD	Goodell, J.A. et al., "Preparation and release characteristics of tobramycin-impregnated polymethylmethacrylate beads," <i>American Journal of Hospital Pharmacy</i> 43(6): 1454-1461, June 1986.
	CE	Gutowska, A. et al., "Heparin release from thermosensitive hydrogels," <i>Journal of Controlled Release</i> 22(2): 95-104, 1992.
	CF	Harsh and Gehrke, "Controlling the swelling characteristics of temperature-sensitive cellulose ether hydrogels," <i>Journal of Controlled Release</i> 17(2): 175-186, 1991.
	CG	Heller, J. et al., "Chemically Self-Regulated Drug Delivery Systems," in <i>Polymers in Medicine III</i> , C. Migliaresi et al. (eds.), Elsevier Science Publishers, Amsterdam, 1998, pgs. 175-188.
	CH	Hoffman, A.S. et al., "Characterizing Pore Sizes and Water 'Structure' in Stimuli-Responsive Hydrogels," <i>Polymer Preprints</i> 34(1): 828, March 1993.
	CI	Hoffman, A.S., "Application of Thermally Reversible Polymers and Hydrogels in Therapeutics and Diagnostics," <i>Journal of Controlled Release</i> 6: 297-305, 1987.
	CJ	Hoffman, A.S., "Thermally Reversible Hydrogels Containing Biologically Active Species," in <i>Polymers in Medicine III</i> , C. Migliaresi et al. (eds.), Elsevier Science Publishers, Amsterdam, 1998, pgs. 161-167.
↓	CK	Holland, S.J. et al., "Polymers for Biodegradable Medical Devices. 1. The Potential of Polyesters as Controlled Macromolecular Release System," <i>Journal of Controlled Release</i> 4: 155-180, 1986.
BF	CL	Johnston, T.P. et al., "Sustained Delivery of Interleukin-2 from a Poloxamer 407 Gel Matrix Following Intraperitoneal Injection in Mice," <i>Pharmaceutical Research</i> 9(3): 425-434, 1992.

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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO
	DB				

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BP	DC	Katono, H. et al., "Thermo-responsive swelling and drug release switching of interpenetrating polymer networks composed of poly(acrylamide-co-butyl methacrylate) and poly(acrylic acid)," <i>Journal of Controlled Release</i> 16: 215-228, 1991.
	DD	Kim, S.W. et al., "Hydrogels: Swelling, Drug Loading, and Release," <i>Pharmaceutical Research</i> 9(3): 283-290, 1992.
	DE	Kim, Y-H et al., "pH/Temperature-sensitive polymers for macromolecular drug loading and release," <i>Journal of Controlled Release</i> 28: 143-152, 1994.
	DF	Kono, K. et al., "Temperature-sensitive liposomes: liposomes bearing poly(N-isopropylacrylamide)," <i>Journal of Controlled Release</i> 30: 69-75, 1994.
	DG	Kost and Langer, "Responsive polymeric delivery systems," <i>Advanced Drug Delivery Reviews</i> 46: 125-148, 2001.
	DH	Langer and Folkman, "Controlled Release of Macromolecules from Polymers," in <i>Biomedical Polymers. Polymeric Materials and Pharmaceuticals for Biomedical Use</i> , Goldberg and Nakajima (eds.), Academic Press, New York, 1980, pgs. 113-137.
	DI	Miyazaki, S. et al., "Drug release from oral mucosal adhesive tablets of chitosan and sodium alginate," <i>International Journal of Pharmaceutics</i> 118(2): 257-263, May 16, 1995.
	DJ	Nagy, A. et al., "Design, synthesis and <i>in vitro</i> evaluation of cytotoxic analogs of bombesin-like peptides containing doxorubicin or its intensely potent derivative, 2-pyrrolinodoxorubicin," <i>Proc. Natl. Acad. Sci. USA</i> 94: 652-656, January 1997.
↓	DK	Nagy, A. et al., "Synthesis and biological evaluation of cytotoxic analogs of somatostatin containing doxorubicin or its intensely potent derivative, 2-pyrrolinodoxorubicin," <i>Proc. Natl. Acad. Sci. USA</i> 95: 1794-1799, February 1998.
BP	DL	Okana, T. et al., "Temperature-responsive poly(N-isopropylacrylamide) as a modulator for alteration of hydrophilic/hydrophobic surface properties to control activation/inactivation of platelets," <i>Journal of Controlled Release</i> 36: 125-133, 1995.

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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO
	EB				

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BF	EC	Okano, T., "Molecular Design of Stimuli-Responsive Hydrogels for Temporal Controlled Drug Delivery," in <i>1995 Proceedings of the 22<sup>nd</sup> International Symposium on Controlled Release of Bioactive Materials</i> , Controlled Release Society, Deerfield, IL, 1995, pgs. 111-112.
	ED	Paavola, A. et al., "Controlled Release of Lidocaine from Injectable Gels and Efficacy in Rat Sciatic Nerve Block," <i>Pharmaceutical Research</i> 12(12): 1997-2002, 1995.
	EE	Palasis and Gehrke, "Permeability of responsive poly(N-isopropylacrylamide) gel to solutes," <i>Journal of Controlled Release</i> 18: 1-12, 1992.
	EF	Peppas, N.A., "III Fundamentals of pH- and Temperature-Sensitive Delivery Systems," <i>Paperback APV, 33 (Pulsatile Drug Delivery)</i> , pgs. 41-56, 1993.
	EG	Pitt, C.G., "The controlled parenteral delivery of polypeptides and proteins," <i>International Journal of Pharmaceutics</i> 59: 173-196, 1990.
	EH	Rhine, W.D. et al., "Polymers for Sustained Macromolecule Release: Procedures to Fabricate Reproducible Delivery Systems and Control Release Kinetics," <i>Journal of Pharmaceutical Sciences</i> 69(3): 265-270, March 1980.
	EI	Schiff, P.B. et al., "Promotion of microtubule assembly <i>in vitro</i> by taxol," <i>Nature</i> 277: 665-667, February 22, 1979.
	EJ	Serres, A. et al., "Temperature and pH-sensitive Polymers for Human Calcitonin Delivery," <i>Pharmaceutical Research</i> 13(2): 196-201, 1996.
↓	EK	Sershen and West, "Implantable, Polymeric systems for modulated drug delivery," <i>Advanced Drug Delivery Reviews</i> 54: 1225-1235, 2002.
BF	EL	Shiraishi, S. et al., "Controlled-Release Preparation of Indomethacin Using Calcium Alginate Gel," <i>Biological &amp; Pharmaceutical Bulletin</i> 16(11): 1164-1168, November 1993.

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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO
	FB				

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BF	FC		Thacharodi and Rao, "Collagen-chitosan composite membranes for controlled release of propranolol hydrochloride," <i>International Journal of Pharmaceutics</i> 120(1): 115-118, June 16, 1995.
	FD		Wani, M.C. et al., "Plant Antitumor Agents. VI. The Isolation and Structure of Taxol, a Novel Antileukemic and Antitumor Agent from <i>Taxus brevisolia</i> ," <i>Journal of the American Chemical Society</i> 93(9): 2325-2327, May 5, 1971.
	FE		Wu and Lee, "Preparation and Characterization of Thermal- and pH-Sensitive Nanospheres," <i>Pharmaceutical Research</i> 10(10): 1544-1547, 1993.
	FF		Yao, K.D. et al., "pH-Sensitivity of Hydrogels Based on Complex Forming Chitosan: Polyether Interpenetrating Polymer Network," <i>Journal of Applied Polymer Science</i> 48(2): 343-354, April 10, 1993.
	FG		Yoshida, R. et al., "Positive thermosensitive pulsatile drug release using negative thermosensitive hydrogels," <i>Journal of Controlled Release</i> 32: 97-102, 1994.
	FH		Yu and Grainger, "Novel Thermo-sensitive Amphiphilic Gels: Poly N-isopropylacrylamide-co-sodium acrylate-co-n-N-alkylacrylamide Network Synthesis and Physicochemical Characterization," <i>Polymer Preprints</i> 34(1): 820-821, March 1993.
↓	FI		Yu and Grainger, "Thermo-sensitive Swelling Behavior in Crosslinked N-isopropylacrylamide Networks: Cationic, Anionic and Ampholytic Hydrogels," <i>Polymer Preprints</i> 34(1): 829-830, March 1993.
BF	FJ		Zhou and Smid, "Physical Hydrogels of Associative Star Polymers," <i>Polymer Preprints</i> 34(1): 822-823, March 1993.
	FK		
	FL		
EXAMINER /Blessing Puhara/			DATE CONSIDERED 09/18/2006
* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).			

5/19/2004

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FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 110129.430	APPLICATION NO. 10/673,046
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS David M. Gravett et al.			
		FILING DATE September 26, 2003	GROUP ART UNIT 1614		

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
BF	GA	5,716,981	02/10/98	Hunter et al.	514	449	
	GB	5,886,026	03/23/99	Hunter et al.	514	449	
	GC	5,994,341	11/30/99	Hunter et al.	514	210	
	GD	6,495,579	12/17/02	Hunter	514	365	
	GE	6,506,411	01/14/03	Hunter et al.	424	501	
	GF	6,515,016	02/04/03	Hunter	514	449	
	GG	6,544,544	04/08/03	Hunter et al.	424	424	
	GH	6,689,803	02/10/04	Hunter	514	365	
	GI	2002/0013298	01/31/02	Hunter	514	113	
	GJ	2002/0022055	02/21/02	Signore	424	486	
	GK	2002/0052404	05/02/02	Hunter et al.	514	449	
	GL	2002/0119202	08/29/02	Hunter et al.	424	501	
	GM	2002/0165265	11/07/02	Hunter et al.	514	449	
	GN	2003/0004209	01/02/03	Hunter et al.	514	449	
	GO	2003/0124197	07/03/03	Signore et al.	424	499	
	GP	2003/0157187	08/21/03	Hunter	424	600	
	GQ	2003/0203976	10/30/03	Hunter et al.	514	772.3	
▼	GR	2003/0216758	11/20/03	Signore	606	151	
BF	GS	2004/0043052	03/04/04	Hunter et al.	424	426	

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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